

Listing of Claims

Claims 1 to 63 (cancelled)

64. (new) A uniform dry powder composition comprising agglomerates of fine particles of one pharmacologically active agent which is mometasone furoate and particles of lactose wherein the composition has a bulk density of from about 0.29 to about 0.38 g/cm³, and wherein the composition is substantially homogeneous.

65. (new) A composition according to claim 64, wherein the composition has a bulk density of from about 0.31 g/cm³ to about 0.38 g/cm³.

66. (new) A composition according to claim 65, wherein the composition has a bulk density of from about 0.35 g/cm³ to about 0.38 g/cm³.

67. (new) A composition according to claim 66, wherein the composition has a bulk density of from about 0.36 g/cm³ to about 0.38 g/cm³.

68. (new) A composition according to claim 66, wherein the composition has a bulk density of from about 0.35 g/cm³ to about 0.36 g/cm³.

69. (new) A composition according to claim 65, wherein the composition has a bulk density of from about 0.31 g/cm³ to about 0.36 g/cm³.

70. (new) A composition according to claim 68, wherein the composition has a bulk density of 0.35 g/cm³.

71. (new) A composition according to claim 64, wherein the mometasone furoate and lactose particles have a particle size of less than about 10 μm.

72. (new) A composition according to claim 71, wherein the mometasone furoate particles and lactose particles have a particle size of from about 5 μm to about 10 μm.

73. (new) A composition according to claim 71, wherein the mometasone furoate particles and lactose particles have a particle size of from about 6.8 μm to about 10 μm.

74. (new) A composition according to claim 71, wherein the mometasone furoate particles and lactose particles have a particle size of from about 5 μm to about 6.8 μm.

75. (new) A composition according to claim 71, wherein the mometasone furoate particles and lactose particles have a particle size of about 4.7 μm.

76. (new) A composition according to claim 71, wherein the mometasone furoate and lactose particles have a particle size of less than 6.8 μm .

77. (new) A composition according to claim 64, wherein the mometasone furoate is anhydrous mometasone furoate.

78. (new) A composition according to claim 64, wherein the lactose is anhydrous lactose.

79. (new) A composition according to claim 64, wherein the lactose is hydrous lactose.

80. (new) A composition according to claim 77, wherein the lactose is anhydrous lactose.

81. (new) A composition according to claim 77, wherein the lactose is hydrous lactose.

82. (new) A process for preparing a uniform dry powder composition comprising agglomerates of fine particles of one pharmacologically active agent which is mometasone furoate and particles of lactose wherein the composition has a bulk density of from 0.29 to 0.38 g/cm^3 and the composition is substantially homogeneous, the process comprising:

(a) micronizing particles of mometasone furoate and particles of lactose, so that at least one of the mometasone furoate and the lactose has a preselected amount of convertible amorphous content which is capable of being converted to crystalline form upon exposure to a preselected stimulus, the convertible amorphous content being provided in an amount which is sufficient to allow for the formation of agglomerates;

(b) agglomerating the particles of mometasone furoate and lactose while maintaining the preselected amount of convertible amorphous content; and

(c) exposing the convertible amorphous content within the agglomerates to the preselected stimulus to convert the convertible amorphous content to a crystalline form.

83. (new) A process according to claim 82 wherein the stimulus is an atmosphere having a humidity sufficient to cause substantially complete conversion of the convertible amorphous content within the agglomerates to a crystalline form.

84. (new) A process according to claim 83, wherein the mometasone furoate is anhydrous mometasone furoate.

85. (new) A process according to claim 83, wherein the lactose is anhydrous lactose.

86. (new) A process according to claim 83, wherein the lactose is hydrous lactose.

87. (new) A process according to claim 84, wherein the lactose is hydrous lactose.

88. (new) A process according to claim 84, wherein the lactose is anhydrous lactose.

89. (new) A process for preparing a uniform dry powder composition comprising agglomerates of fine particles of one pharmacologically active agent which is mometasone furoate and particles of lactose wherein the composition has a bulk density of from 0.29 to 0.38 g/cm³ and the composition is substantially homogeneous, the process comprising:

micronizing particles of mometasone furoate and particles of lactose to obtain micronized mometasone furoate particles and lactose particles, wherein at least one of mometasone furoate and the lactose has a convertible amorphous content;

mixing the micronized mometasone furoate particles and lactose particles to obtain a substantially homogenous mixture, and agglomerating the mixture and maintaining the convertible amorphous content; and

spheronizing the agglomerates, and exposing the convertible amorphous content within the agglomerates to an atmosphere having a humidity sufficient to cause substantially complete conversion of the convertible amorphous content within the agglomerates to a crystalline form.

90. (new) A process according to claim 89, wherein the mometasone furoate is anhydrous mometasone furoate.

91. (new) A process according to claim 89, wherein the lactose is anhydrous lactose.

92. (new) A process according to claim 89, wherein the lactose is hydrous lactose.

93. (new) A process according to claim 90, wherein the lactose is anhydrous lactose.

94. (new) A process according to claim 90, wherein the lactose is hydrous lactose.